

Peer Review

Review of: "Does Accreditation Improve the Protection of Human Research Subjects and the Quality of Institutional Review Board Reviews?"

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Discussion of the possible positive and negative effects of accreditation is important right now, as institutions receive more pressure to become accredited while at the same time facing substantial decreases in research funding and infrastructure support. I appreciated the author laying out the history of accreditation, though I agree with one of the other reviewers that mention should be made of the 2023 GAO report and the various responses to the report; what I recall about some of the HRPP responses was a question about how to measure quality. The quality markers the author lists do not speak to actual review quality. You can have an absolutely useless study that does not have any adverse events--the lack of adverse events does not indicate that the study is good or that the review and approval were sound. Do you assess quality based on meeting regulatory requirements? Based on consistency of reviews over time? Research into what the IRB community considers indicators of quality would be a great way to move forward; until we identify quality indicators, we cannot determine whether accreditation improves quality.

The explanation of what independent IRBs are seems out of place where it is currently. It might make more sense to move that paragraph down to the paragraph outlining how many independent IRBs are accredited. Are all standalone IRBs for-profit? At one point, North Star Review Board was an independent IRB acting as a nonprofit. Does for-profit or nonprofit status change the accreditation process?

That said, there is still value in discussing the pros and cons of accreditation as well as the history of accreditation. The author provides the list of benefits AAHRPP supplies in their marketing. Are those benefits actually received by the institutions? Looking at trends in federal agency audit findings for

accredited versus unaccredited institutions might indicate whether accredited agencies have an advanced standing with federal agencies, or it might just indicate that there are fewer findings due to the rigorous standards of accreditation. Anecdotally, I know some accredited institutions will not rely on institutions whose IRBs are not accredited, so there may be some validity to AAHRPP's statement about favorable treatment from sponsors and others. One way or another, it would be worth interrogating the points AAHRPP makes in favor of accreditation if considering whether accreditation brings value.

The author brings up the financial cost of initial accreditation, which can be prohibitive for cash-strapped organizations. Adding an assessment of the FTEs involved in preparing for and maintaining accreditation could add value, though it might take reaching out to some accredited institutions about what their accreditation process involved.

I would also be interested in seeing a discussion of the extra-regulatory elements required for accreditation, as I have been told that many requirements are not specifically called for in regulations. Is there value in the extra-regulatory elements that warrants any additional process time or effort? Are the initial and ongoing costs of accreditation more than some institutions can bear? If so, do those institutions eventually just phase out their IRBs if they cannot keep up?

There is a lot to discuss regarding accreditation. Adding some of these points to the manuscript could make it more relevant for those trying to assess whether accreditation is a worthwhile endeavor while also advocating for research into IRB quality.

Declarations

Potential competing interests: No potential competing interests to declare.